CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE QRA AND SURVEILLANCE INVESTIGATIONS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees by outlining the steps involved in the conduct of on-site investigations of CAH's customers to obtain information regarding their potential risk for diversion of regulated drugs.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, to meet the obligations set forth in the Administrative Memorandum of Agreement (MOA) effective May 14, 2012, and to meet or exceed DEA's expectations of distributors that have been communicated to CAH through informal, non-binding communications.

1.3 The purpose of this procedure is also to enable investigators to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site investigations after receiving permission from the Director or Vice President of Supply Chain Integrity.

2.0 SCOPE

This procedure applies when CAH Quality and Regulatory Affairs (QRA) determines that an on-site investigation of a DEA-registered customer is necessary to meet the objectives outlined in Section 1.0 above. The procedures outlined apply to all retail pharmacies, including chain pharmacies. The procedure also applies to KINRAY and PARMED retail customers and dispensing physician customers. This document also provides the investigators the ability to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site visits.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/~~	Detecting and Reporting Suspicious Orders and Responding To Threshold Events

DEFENDANT EXHIBIT
CAH-WV-00070

~~CAD-C007.docx" }~~	
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx" }~~	QRA Site Visit Form
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form2.xlsx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form2.xlsx" }~~	Surveillance Site Visit Form
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }~~	Large Volume – Tactical and Analytical Committee Review Process

4.0 RESPONSIBILITIES

The designated CAH employee(s) responsible for Suspicious Order Monitoring (SOM) have the primary responsibility for compliance to this procedure.

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC)	The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.
Case	An investigation of a customer conducted after a threshold event or after Cardinal Health learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
Case File	An individual file created within the case management system which is unique to a specific case and identified through the customer's DEA number. The file will serve as the investigative log in which all information collected regarding a specific case is to be documented.
Case Management System	A manual or electronic system used by the Director to efficiently and effectively monitor and manage each case.
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
Customer	Any retail pharmacy customer regulated and properly licensed in good standing with the DEA and any other agencies as required by state or federal law for the purchase of regulated drugs.
Customer Category	The category to which the customer belongs based on three month average monthly volume for the drug family leading to the customer site visit request as set by the Vice-President
DEA	Drug Enforcement Administration.
Director	Director, Supply Chain Integrity and Regulatory Operations or his designee. Note: the Director is a licensed pharmacist.
Distrack	Cardinal Health warehouse management system that is utilized by Pharmaceutical Distribution Centers. This is an automated management system and includes information such as customer names, inventory, orders, shipments, threshold, etc.
Investigator	An individual authorized by Cardinal Health to conduct on-site investigations of customers at the direction of the Director. These individuals include QRA employees, designated Cardinal Health employees, or authorized outside

contractors.

PBC Cardinal Health sales personnel. Acronym for Pharmacy Business Consultant.

Regulated Drug Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.

SOM Suspicious Order Monitoring

Suspicious Order A customer's order for a:

- Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency;
- List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or
- Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event The initial held order for a regulated drug which exceeds the threshold set for a specified licensed customer. This is created by a DEA#, Base Code and Threshold Limit combination. These thresholds are designed as trigger points to review and evaluate an order. Orders that reach the threshold are not necessarily suspicious. An evaluation is required once an order reach the thresholds to determine if they are suspicions.

Vice-President Vice-President, Anti-Diversion & Supply Chain Integrity & Sr. Regulatory Counsel or his designee. Note: the Vice-President is a licensed pharmacist.

6.0 PROCEDURE

6.1 Receipt and Assignment of Cases

6.1.1 Receipt of Cases

6.1.1.1 Site visit cases are received from two sources:

a. QRA Pharmacists request a site-visit to a pharmacy based on the totality of circumstances for suspicious orders (or order lines) following SOP [

HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"~~ }.

b. The Large Volume Tactical and Analytical Committee selects certain customers considered to present a higher risk of diversion based on criteria like volume of controlled substance purchases, growth in controlled substance purchases and others factors following SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"~~ }.

6.1.2 Assignment of Cases

6.1.2.1 The Director assigns cases in customer categories as determined by current procedure to QRA site visit investigators and/or external contractors.

6.1.2.2 QRA investigators or contractors must complete the site visits within a reasonable period of time (**e.g.**, within 30 calendar days) and submit the report within a reasonable period of time after the visit (**e.g.**, 10 calendar days)

6.1.2.3 The Director assigns cases in customer categories as determined by current policy to Sales Team or other CAH employees for surveillance site visit and QRA Analytics team for pharmacy data collection.

6.1.2.4 Sales team or other CAH employees must complete the surveillance site visits within a reasonable period of time (**e.g.**, within 7 calendar days) and submit the report to QRA analytics within a reasonable period of time after the surveillance visit (**e.g.**,10 calendar days)

6.1.2.5 For surveillance visits, QRA Analytics team must complete data gathering and analysis within a reasonable period of time (**e.g.**, 7 calendar days) and submit the completed surveillance report to Director or Vice-President for review

6.1.2.6 After review and approval by the Director or Vice-President, the file will be uploaded on the QRA content manager and available for review by the QRA pharmacist

6.2 QRA Investigator (or Contractor), or other CAH employees Site Visit Process

6.2.1 Background Preparation

6.2.1.1 Contact relevant PBC or Sales Manager to inform of the site visit and arrange for the site visit

6.2.1.2 In preparation for the site visit, where possible and available, the investigator can choose to request from the pharmacist-in-charge, pharmacy owner or their representative (through the PBC or Sales Point of Contact, or other CAH employees where necessary) data that would assist in the evaluation of the pharmacy. The preparation of the report can be initiated with the information obtained via phone, fax of email.

6.2.1.3 Gather and review the information possessed by CAH regarding the case and the licensed customer. Depending on the case and customer, this may include, but is not limited to, information located in the following systems:

a. SOM / Anti-Diversion Centralization system information
b. Data from Tableau Reports generated from customer purchase history
c. Review activity of Controlled Substance (CS) drug identified in site visit request along with activity of all CS drug family to ascertain the need for closer look at those CS drugs
d. Content Manager (either through ADC or directly from Content Manager)
e. Distrack or any other relevant source

6.2.1.4 Perform internet search - **e.g.**, some helpful Internet resources include the following:

a. Google
b. Reverse address and phone directory
c. Location photographs from Google Earth or Yahoo Maps
d. Global Internet Management (DEA # verification)
e. Secretary of State (Corporate information)
f. Department of Health
g. State Board of Pharmacy
h. ZABA Search (personal information)

6.2.1.5 Scan any items of concern (**e.g.**, disciplinary actions against the pharmacy or its top prescribing physicians, records of DEA license suspension, and current investigations).

6.2.1.6 Record relevant information from background search on the site visit form and answer if the background research was acceptable on the pharmacy. Explain if background research was not acceptable.

6.2.2 Site Visit

6.2.2.1 Information collected and observed during the site visit should be reported and recorded on the site visit report template provided by the director.

6.2.2.2 Follow the site visit report template and ask questions in dispensing information, dispensing analysis, know-your-customer, due-diligence sections.

6.2.2.3 For each section populate the answers as available in the site visit report and follow the worksheet.

6.2.2.4 Seek and record explanations to questions that would help assess if the controlled substances prescriptions are being filled for legitimate medical purpose.

6.2.3 Completing Site Visit Report Sections

6.2.3.1 Dispensing information section contains questions on;

a. Average number of total prescriptions per day
b. Average number of total prescriptions paid in cash per day
c. Average number of controlled substance prescriptions per day
d. Average number of controlled substance prescriptions paid in cash per day
e. Higher level of dispensing of most likely to be diverted strengths of Oxycodone, Hydrocodone, Alprazolam and all other controlled substances of interest

The actual numbers may be obtained from the customer. If the actuals are unavailable, the investigator should request the pharmacist to provide an estimate.

- Explanations should be sought if the percentage of controlled substance prescriptions paid for in cash is significantly higher than benchmarks.
- Explanations should also be sought if the percentage of controlled substance prescriptions paid in cash is significantly higher (**e.g.**, larger than 4%) than that of the non-controlled substances paid for in cash.
- Explanations should also be sought if a high level dispensing of most likely diverted strengths is observed including details of prescribers contributing to the higher level dispensing of most likely diverted strengths of controlled substances.

6.2.3.2 Dispensing analysis section of the report requests average monthly dosage units (over the previous 3 to 6 months depending on data availability) dispensed for 13 most likely to be diverted drug families. If this data is not readily available, use CAH sales data to complete this section to get an idea of the monthly usage rate

of the pharmacy. Complete this section only for those controlled substance drug products that are of interest to CAH at this pharmacy – drugs of interest include drug families (among the 13 most likely diverted drug families) that were flagged as part of the suspicious order reporting process, Large Volume Tactical & Analytical Committee review process or any from any other QRA processes or sources.

Analyze dispensing data for the following substances:

a. Oxycodone
b. Hydrocodone
c. Alprazolam
d. Hydromorphone
e. Oxymorphone
f. Carisoprodol
g. Methadone
h. Fentanyl
i. Morphine Sulfate
j. Zolpidem
k. Clonazepam
l. Methylphenidate
m. Amphetamine salts

6.2.3.3 Based on CAH sales data in Tableau or other tools, investigate if any of the drug families of interest experience disproportionate growth in the past 12 months and investigate the reasons why.

6.2.3.4 Know-your-customer section addresses such questions as:

a. Who are the main healthcare providers in the pharmacy's draw area?
b. What are the estimates of total, Controlled Substance (Schedule 2) and Controlled Substance (Schedules 3-5) purchased across all wholesalers at the pharmacy customer?

6.2.3.5 Due diligence section of contains questions on:

a. Whether the pharmacist employs his or her corresponding responsibility;
b. Explanation of the due-diligence steps taken by the pharmacist to ensure that controlled substance prescriptions are being filled for legitimate purposes;
c. Questions on possible diversion indications such as:
   - There were long queues outside the pharmacy
   - The patients and customers at the pharmacy were NOT congruent with the demographics and economics of the area?
   - Disproportional Out-of-state vehicles were parked outside the

pharmacy
- Any evidence of illicit drug use around the pharmacy (used syringes, empty prescription containers etc.)
- Presence of any mailing materials or any other evidence of an internet pharmacy?
- Any other obvious signs of diversion at the pharmacy during the site visit?

6.2.4 Site Visit Assessment

6.2.4.1 Based on the totality of observations and analysis made by the investigator, determine whether the pharmacy needs an immediate re-evaluation by the originator of the site visit request (Director, Vice-President or Large Volume – Tactical and Analytical Committee).

6.2.4.2 Provide any additional explanation or observations that the corporate reviewer (Director, Vice-President or Large Volume – Tactical and Analytical Committee) may need to consider in their evaluation.

6.2.4.3 The Corporate Reviewer (Director, Vice-President or Large Volume Tactical and Analytical Committee Representative) will complete the Reviewer Assessment and Decision section, record the decision and reasons behind the decision according to procedures specified in [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"~~ }.

6.3 Sales, QRA Investigator, other CAH employees or Contract Surveillance Site Visit Process

6.3.1 Background Preparation

6.3.1.1 The QRA analytics team will begin data collection directly from the pharmacy for retail independent pharmacies and from corporate offices for chain pharmacies.

6.3.1.2 Surveillance investigator will visit the customer unannounced

6.3.2 Site Visit Report Completion

6.3.2.1 The surveillance investigator must complete basic customer information, due diligence and investigator assessment sections in the surveillance site visit report template.

6.3.2.2 The QRA analytics team will complete the remaining sections of the surveillance site visit report wherever data can be obtained from the customer:

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Investigators should avoid language that is speculative or subject to multiple interpretations in the reports and case notes.

7.1.2 The findings must be based on factual data, site visit observations and analysis of data gathered prior and during site visits.

7.1.3 Where appropriate and available, analysis of dispensing data, tableau data and other information must be documented in the case notes or threshold analysis files.

7.2 Documentation Retention

7.2.1 All documents must be loaded onto CAH QRA Content Manager within a reasonable period of time.

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Pharmaceutical Distribution

ON-SITE QRA AND SURVEILLANCE INVESTIGATIONS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Steve Morse PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3006	06 Jun 2012	Modify	Yes	Corporate	COs & DOs Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the on-site investigation process.					
Change Description and Justification					
Document was revised to reflect the updated on-site QRA and surveillance investigations, two new forms were created to aid in the investigators.					